

CLAIMS:

1. A process for producing a leukocyte bank suitable for CAT therapy comprising the steps of:

- (a) providing a blood sample from a healthy donor individual;
- (b) selectively separating leukocytes from the sample;
- (c) collecting the separated leukocytes in a holding vessel;
- (d) transferring two or more aliquots of the separated leukocytes to independent double containment storage vessels, wherein each of the storage vessels contains, or is in fluid communication with, a cryopreservation medium;
- (e) mixing each aliquot with the cryopreservation medium within each storage vessel;
- (f) cryogenically preserving each of the two or more aliquots within each of the storage vessels;
- (g) retrievably depositing each of the two or more storage vessels containing the aliquots of preserved leukocytes into two or more independent storage systems to produce a leukocyte bank which exhibits deposit redundancy;

wherein:

- (h) steps (b) to (g) are conducted within a closed or functionally closed system and are applied iteratively to a series of blood samples from different healthy donor individuals; and
- (i) the process further comprises digitally storing information obtained from each donor individual in a digital information unit so as to permit matching of leukocyte deposit and donor for later autologous transplantation.

2. The process of claim 1 wherein the cryogenic preservation step (f) comprises freezing to a temperature at or below about -160°C.

3. The process of claim 1 wherein the cryogenic preservation step (f) comprises freezing to a temperature at or below about -269°C.

4. The process of any one of the preceding claims wherein the cryopreservation medium comprises a penetrating cryoprotectant.

5. The process of claim 4 wherein the penetrating cryoprotectant comprises DMSO.

6. The process of claim 5 wherein the DMSO is present at a concentration of up to 10%.

7. The process of any one of claims 4 to 6 wherein cryopreservation medium further comprises an anticoagulant.

8. The process of claim 7 wherein the anticoagulant comprises an anticoagulant selected from acid citrate dextrose, EDTA and heparin.

9. The process of any one of claims 4 to 8 wherein the cryopreservation medium further comprises a nuclease.

10. The process of claim 9 wherein the nuclease comprises ribonuclease and/or deoxyribonuclease.

11. The process of any one of claims 4 to 10 wherein the cryopreservation medium further comprises a physiologically acceptable medium.
- 5 12. The process of claim 11 wherein the physiologically acceptable medium is phosphate buffered saline.
13. The process of any one of claims 4 to 12 wherein the cryopreservation medium further comprises a proteinaceous and/or sugar and/or polysaccharide composition.
- 10 14. The process of claim 13 wherein the proteinaceous composition comprises blood serum or a blood serum component.
15. The process of claim 14 wherein the proteinaceous composition comprises blood albumin (e.g. bovine serum albumin or human serum albumin).
- 15 16. The process of claim 15 wherein the proteinaceous composition comprises human blood serum isolated from the blood sample of the donor individual.
17. The process of any one of the preceding claims wherein the healthy donor individual:
- 20 (a) is predisposed to a leukocyte deficiency; and/or
- (b) is not in remission from a leukocyte deficiency; and/or
- (c) is juvenile, adolescent or adult; and/or
- (d) is at risk of developing a leukocyte deficiency; and/or
- 25 (e) is a human individual between the ages of about 12 to 30 (e.g. 15 to 25); and/or
- (f) has a fully-developed immune system.
18. The process of any one of the preceding claims wherein the blood sample is an isolated blood sample.
19. The process of claim 18 wherein the isolated blood sample has a volume of 450 to 500ml.
- 30 20. The process of any one of the preceding claims wherein steps (b) to (g) are applied iteratively to a series of blood samples from the same healthy donor individual.
21. The process of claim 20 wherein steps (b) to (g) are applied to 2-12 samples taken from the same healthy
- 35 donor individual over the course of one year.
22. The process of any one of the preceding claims wherein the leukocytes separated in step (b) comprise (or consist essentially of):
- 40 (a) granulocytes; and/or
- (b) lymphocytes; and/or
- (c) monocytes.

23. The process of claim 22 wherein the separation step (b) comprises the selective separation of a particular class or type of leukocyte.

24. The process of claim 24 wherein the separation step (b) comprises the selective separation of B-cells and/or T-cells and/or dendritic cells and/or mixtures thereof.

25. The process of any one of the preceding claims wherein the information stored in step (i) comprises:

- (a) genetic information; and/or
- (b) the date at which the blood sample was collected from the donor individual; and/or
- (c) the age and sex of the donor individual; and/or
- (d) the clinical status of the donor individual; and/or
- (e) a medical history of the donor individual; and/or
- (f) biographical data identifying the donor individual; and/or
- (g) details of the processing and storage conditions used; and/or
- (h) data identifying the person(s) responsible for processing the sample(s).

26. The process of claim 25 wherein the information comprises genetic information selected from:

- (a) sequence information relating to one or more gene(s); and/or
- (b) single nucleotide polymorphism (SNP) data; and/or
- (c) a genetic fingerprint.

27. The process of any one of the preceding claims wherein the digital information unit comprises at least one digital computer.

28. The process of any one of the preceding claims further comprising the step of labelling the storage vessels of step (f) with information sufficient to permit matching of the leukocyte deposit and donor.

29. The process of any one of the preceding claims further comprising the step of labelling the storage vessels of step (f) with information:

- (f) describing the contents of the vessel (for example, sample size, number and/or volume); and/or
- (g) identifying the leukocyte bank; and/or
- (h) recording the date at which the blood sample was collected from the donor individual; and/or
- (i) comprising a statement that each package is for single patient use only; and/or
- (j) comprising instructions for opening, aseptic presentation and further storage.

29. The process of claim 28 wherein the labelling comprises physical attachment of a bar code to the storage vessels.

30. The process of any one of the preceding claims wherein the leukocytes are treated:

- (a) *in vivo* prior to provision of the blood sample;
- (b) *in vitro* prior to separation step (b);
- (c) *in vitro* after separation step (b) but prior to preservation step (f);
- (d) *in vitro* after preservation step (f).

31. The process of any one of the preceding claims wherein the leukocytes are selectively separated and or collected from the sample by:

(a) isolated leukapheresis;

5 (b) continuous or interrupted flow centrifugation leukapheresis (e.g. automated continuous or interrupted flow centrifugation leukapheresis);

(c) continuous or interrupted flow filtration leukapheresis (e.g. automated continuous or interrupted flow filtration leukapheresis);

(d) gravity leukapheresis;

10 (e) batch centrifugal separation and collection (e.g. by bag pressing).

32. A process for producing a leukocyte composition for autotransplantation into a donor individual comprising the steps of:

(e) producing a leukocyte cell bank by the process of any one of the preceding claims;

15 (f) matching the donor individual with a leukocyte deposit to identify an autologous leukocyte deposit using the information stored in step (h);

(g) retrieving a storage vessel containing an aliquot of preserved autologous leukocytes; and

(h) revitalizing the preserved autologous leukocytes to produce a leukocyte composition for autotransplantation into the donor individual.

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33. The process of claim 32 wherein the leukocytes are revitalized by thawing and/or dilution.

34. The process of claim 33 for producing a leukocyte composition for restorative autotransplantation.

25 35. A leukocyte bank obtainable (or obtained) by the process of any one of claims 1 to 31.

36. A leukocyte composition obtainable (or obtained) by the process of any one of claims 32 to 34.

37. The leukocyte composition of claim 36 for use in therapy or prophylaxis.

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38. Use of the leukocyte composition of claim 36 for the manufacture of a medicament for use in autotransplantation (e.g. in restorative autotransplantation).